EMM
Exact Medical Manufacturing, Inc.

SEP 2 0 2010

Sec. 6 510(k) Summary – EMM Surgical Drape-Spunlace w/PE Sides

K101688

510(k) Summary for Exact Medical Manufacturing Inc., EMM Surgical Drape-Spunlace w/PE Sides

Date Summary was Prepared	June 10,2010
510(k) Submitter	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Primary Contact for this 510(k) Submission	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Device Common Name	Surgical Drape
Trade Name	EMM Surgical Drape-Spunlace w/PE Sides, ***Model 13-004***
Device Product Codes and Classification Name	KKX, 21CFR878.4370, Surgical Drape and Drape Accessories, Class II
Predicate Device	Medline (Proxima) Surgical Drapes 510(k)964142
Device Description	Exact Medical Manufacturing Surgical Drape -Spunlace w/PE Sides are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. Exact Medical Manufacturing Surgical Drapes-Spunlace w/PE Sides are comprised of Spunlace, Polyethylene, 3M Medical Adhesive Tape.
Intended Use	Exact Medical Manufacturing Surgical Drape -Spunlace w/PE Sides are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination The Exact Medical Manufacturing Surgical Drape-Spunlace w/PE Sides are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.
Technological Characteristics	Exact Medical Manufacturing Surgical Drape-Spunlace w/PE Sides has the same design, material and performance characteristics of the predicate device. ***Additional Summary and Explanation of Technological Characteristics is included in the following Addendum A***
Summary of Testing	Exact Medical Manufacturing Surgical Drape-Spunlace w/PE Sides are substantially equivalent and meet the same acceptance criteria as the predicate device/gown in K964142 Non-clinical performance testing includes: Biocompatibility (cytotoxicity, irritation, sensitization) in compliance with the methods of ISO 10993, Barrier properties, Level 2, tensile, tear strength, flammability, linting and sterility. All results of the testing met acceptance criteria. ***Additional Summary and explanation of non-clinical testing is included in the following Addendum B.***
Substantial Equivalence	The surgical drapes described in this 510(k) submission are substantially equivalent in all specifications and performance compared to the predicate device indentified in K964142 except for minor variations in the widths and lengths.

Addendum A
Summary and Explanation of Technical Characteristics:
EMM SURGICAL DRAPE Spunlace w/PE Sides Predicate Device Comparison Table

Exact Medical Manufacturing - Surgical Drape-Spunlace w/PE Sides *Model #13-004*	Substantially Equivalent	PREDICATE DEVICE Medline (Proxima) Surgical Drapes 510(k)964142
Indications for Use: Exact Medical Manufacturing Surgical Drape -Spunlace w/PE Sides are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination The Exact Medical Manufacturing Surgical Drape-Spunlace w/PE Sides are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.	Substantially Equivalent	**Indications for Use**: devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.
Classification & Code: KKX, Surgical Drapes, 21CFR878.4370, Class II	Substantially Equivalent	**Classification & Code**: KKX, Surgical Drapes, 21CFR878.4370, Class II
Materials & Construction: Spunlace, Polyethylene, Absorbent Reinforcement, 3M Medical adhesive tape	Substantially Equivalent	**Materials & Construction**: Spunlace, Absorbent reinforcement with impervious polyethylene backing, 3M Medical adhesive tape
Barrier properties - AATCC 42:2007, AATCC 127:2008: Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for Use in Health Care Facilities, AAMI PB70:2003 /(R)2009, ' 'el 2 ***ostatic Head = 231 cm PASS***	Substantially Equivalent	Hydrostatic head = 19.5 cm
Sterile (via EO Gas) ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1	Not Applicable	
Sterile Packaging: Chevron peel pouch (coated paper (73gsm), PET12/PE40 film construction), individual CSR internal wrap	Not Applicable	Not Applicable
Non-sterile	Substantially Equivalent	Non-sterile
Biocompatibility: cytotoxicity, irritation and sensitization - ISO 10993-5:1999, **Cytotoxicity**, ISO 10993-10:2002, **Skin Irritation**, ISO 10993-10:2002, **Sensitization** ***Cytotoxicity, Irritation, Sensitization test PASS***	Substantially Equivalent	Biocompatibility: Cytotoxicity, Irritation, Sensitization; PASS
Tear strength - ASTM D5587-08 (no rev.) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure ***Tear strength for Md and Cd exceeds predicate performance***	Substantially Equivalent	Md = 2.5 lbs Cd= 1.4 lbs
Tensile strength - ASTM D5034-09 (no rev.) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) ***Tensile strength for Md and Cd exceeds predicate performance***	Substantially Equivalent	Md = 23 lbs Cd = 12.1 lbs
Flammability - 16CFR1610:2010, Flammability of Clothing Textiles ***Class 1 - PASS***	Substantially Equivalent	Class 1
Lint and other Particles generated in the dry state - ISO 9073-10:2003	Not Applicable	No Test

Addendum B

Non-Clinical Testing Summary: EMM Surgical Drape – Spunlace w/PE Sides, Model # 13-004

Test Article	Finished Good Lot Number	Reference Standard(s)	Description	Accept – Reject Criteria	Pass/ Fail	Test Lab
Model No.13-004 Sterile	0980APA2	AATCC 42:2007 (AAMI PB70:2003 /(R)2009)	Water Resistance: Impact Penetration Test, Level 3	<1.0 gm Blotter water weight gain	Pass	Nelson Labs, Utah, USA
Model No.13-004 Sterile	0980APA2	AATCC 127:2008 (AAMI PB70:2003 /(R)2009)	Water Resistance: Hydrostatic Pressure Test, Level 3	=/> 50 cm hydrostatic resistance	Pass	Nelson Labs, Utah, USA
Model No.13-004 Sterile	0980APA2	ISO 10993-5:1999	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	Evidence of cell lysis or toxicity < 2	Pass	LexaMed, Ohio, USA
Model No.13-005 Sterile	0980APA2	ISO 10993-10:2002	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity (Skin Irritation)	No (0) edema or erythema observed	Pass	LexaMed/NAMSA, Ohio, USA
Model No.13-004 Sterile	0980APA2	ISO 10993-10:2002	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (Skin Sensitization)	No evidence of causing delayed dermal contact sensitization	Pass	LexaMed/NAMSA, Ohio, USA
Model No.13-004 Sterile	0980APA2	16CFR1610:2010	Flammability of Clothing Textiles – Class 1	Class 1 =/> 3.5 sec. average flame spread	Pass	Nelson Labs, Utah, USA
Model No.13-004 Sterile	0980APA2	ASTM D5587-08 (no rev.)	Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	Acceptance criteria not established in recognized standard. Exceeds predicate performance	Pass	Nelson Labs, Utah, USA
Model No.13-004 Sterile	0980APA2	ASTM D5034-09 (no rev.)	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Acceptance criteria not established in recognized standard. Exceeds predicate performance	Pass	Nelson Labs, Utah, USA
Model No.13-004		ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1	SAL of > 10^{-6}	Pass	SCDC, Shanghai, CN LexaMed, Ohio, USA
Model No.13-004 Sterile		ISO 10993-7:2008	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	Average daily dose of EO/ECH shall not exceed 4mg/9mg	Pass	GOALs Sterilization Co. Jiaxing, CN
Model No.13-004 Sterile	0980APA2	ISO 9073-10:2003	Lint and other particles generation in the dry state	Acceptance criteria not established in the recognized standard	Pass	Nelson Labs, Utah, USA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exact Medical Manufacturing, Incorporated
C/O Mr. Robert O. Dean
Compliance Systems International, LLC
1083 Delaware Avenue
Buffalo, New York 14209

SEP 20 2010

Re: K101688
Trade/Device Name: Exact Medical Manufacturing Surgical Drape-Spunlace w/PE Sides, Model 13-004
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: August 20, 2010
Received: August 23, 2010

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sec. 7: - Intended Use

Indications for Use Form

SEP 2 0 2010

Indications for Use:

510(k) Number (if known): ***K101688***

Device Name: Exact Medical Manufacturing Surgical Drape – Spunlace w/PE Sides, ***Model 13-004***

Indications for Use: Exact Medical Manufacturing Surgical Surgical Drape – Spunlace w/PE Sides are sterile or non-sterile single use devices made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

The Exact Medical Manufacturing Surgical Drape – Spunlace w/PE Sides are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization

Prescription Use ___ ____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Elizabeth F. Claverie - Wilk

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101688